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Musculoskeletal system conditions are the leading cause of hospitalization and disability for the U.S. Armed Forces. The Department of Defense pays over $1.5 billion per year to disabled service members, and musculoskeletal conditions account for 40-50% of this amount. This study investigates the effectiveness of an interdisciplinary functional restoration approach to the treatment of Active Duty military from all 4 branches suffering from chronic musculoskeletal pain (CMP). The primary aims of this Functional and Occupational Rehabilitation Treatment Program (FORT) including restoring physical function, retaining soldiers on active duty, and increasing the participants' abilities to effectively manage their pain. These outcomes, as well as socioeconomic variables, will be evaluated immediately following treatment, and at 6, 12, and 18 months follow-up.

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Musculoskeletal; disability; pain; functional restoration; treatment outcomes; cost-effectiveness; interdisciplinary

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INTRODUCTION

Musculoskeletal system conditions are the leading cause of hospitalization and disability for the U.S. Armed Forces. The Department of Defense pays over $1.5 billion per year to disabled service members, and musculoskeletal conditions account for 40-50% of this amount. The medical discharge of one active duty U.S. military member in their twenties has been estimated to cost the government approximately $250,000 in lifetime disability costs, excluding health-care costs. Despite continuous advances in military medicine, the rates of disability cases within the U.S. military have been increasing at an alarming rate, and nearly doubled between 1985 and 1994. Without changes in the current approach to the treatment of musculoskeletal conditions, these trends of increasing disability rates and tremendous associated costs will very likely continue. Fortunately, numerous studies with civilian populations have demonstrated the efficacy of an interdisciplinary chronic pain rehabilitation program (ICPRP) at facilitating return-to-work in workers' compensation patients with occupational musculoskeletal disorders and work disability. Return-to-work rates with this population administered ICPRP often approach 80-85% at one year, compared to no-treatment or standard care comparison groups that demonstrate only a roughly 40% return-to-work. The present research program compares the ICPRP to a standard anesthesiology treatment comparison group. The major hypothesis is that the ICPRP will significantly increase the likelihood of remaining on active duty and qualified for worldwide duty for military personnel suffering from musculoskeletal disorders, and positively impact other socioeconomic outcomes such as health-care utilization. This is a pre-to post-treatment evaluation design, with evaluations conducted immediately before and after treatment, as well as at 6-,12-, and 18-month follow-up periods in order to determine differential outcomes on variables such as return to full duty status, work retention, and additional health-care utilization. The specific aims of the study are to evaluate the efficacy of ICPRP in reducing patient-reported pain symptoms, unnecessary health-care utilization, health-care costs, and number of military members on medical profile, disability, or separated from active duty. Additional aims include improving functioning, increasing the number of military members remaining fit for duty and worldwide qualified, and increasing military members' ability to pass their physical fitness test for their respective military service. In summary, this research project addresses the clear need for clinical research to develop evidence-based assessment and treatment approaches to decrease the enormous cost associated with chronic musculoskeletal conditions within the U.S. Armed Forces.

BODY

In this first year of our grant project, we have accomplished all of the goals originally delineated in our **STATEMENT OF WORK** included in our initial application. It should be noted that, because of the Iraqi war during the first part of 2003, there was a major deployment of personnel from Wilford Hall Medical Center. This interfered somewhat with the early implementation of all aspects of initial activities of YEAR 01. Nevertheless, all tasks have been successfully completed. These are delineated below.

Hire Grant Project Team Members

Classified advertisements were prepared for publication in the hiring of the registered nurse, the research assistant, and the physical therapist/occupational therapist for the study. Subsequently, all of the required grant project team members were hired. These include the following: the study coordinator (Don McGeary, Ph.D.); the physical therapist/occupational

therapist (Mysti Clifton, PT); the research nurse (Karen Leroy, R.N.); the project assistant (Joyce Dudley); and the biostatistician (initially Barbara Foster, who was subsequently replaced by Bill Frawley because of Dr. Foster's retirement). All of these individuals, as well as the rest of the research project team, have completed the required human subjects research training.

Finalize the Formal Treatment Protocols and Required Training

We have finalized the project staff training and integration across the various disciplines involved in the treatment protocols at The University of Texas Southwestern Medical Center at Dallas, Wilford Hall Medical Center, as well as Brooke Army Medical Center. This has resulted in structured protocols for the ICPRP and standard anesthesiology treatment groups that will now run smoothly and allow all patients to gain maximum benefit from all aspects of their treatment. Related to this, the following goals have been achieved:

- Comprehensive provider and patient manuals have been developed, tested, revised and finalized for both treatment programs.
- We have worked extensively to finalize all protocols and/or guidelines, as well as assembling these services into one integrated program for the following treatment components and personnel: (1) The clinical health psychologists at Wilford Hall Medical Center who will be administering the psychological treatment (e.g., individual treatment; stress management/biofeedback; psychoeducational classes). (2) The physical/occupational therapist who will coordinate the functional restoration of patients (e.g., functional capacity evaluation; individual and group exercise programs; didactics). (3) Physicians and nurses who will conduct the medical treatment and oversight of patients (e.g., medication tracking; intervention if injuries or pain worsens).
- We have organized a structured process to accommodate the anticipated flow of patients through the treatment programs.

Development of the Final Assessment-Outcome Measures Database

We have finalized all of the channels for data collection and data flow that will maximize our ability to gather all data in the most reliable, valid and efficient method possible. The biostatistician at The University of Texas Southwestern Medical Center at Dallas has accomplished this, as well as building in quality assurance checks to monitor the integrity of all data collected. We now have a fully functioning data collection system which includes all of the variables proposed in the initial application. Appendix A includes a summary of all the measures in our database.

Final Institutional Review Board Approvals

The final IRB approvals from The University of Texas Southwestern Medical Center at Dallas, Wilford Hall Medical Center, and Brooke Army Medical Center have been accomplished. In response to the Wilford Hall Medical Center's IRB review on November 26, 2002, the ICD was updated to indicate that, if active duty participants are no longer on active duty during the follow-up period, they consent to be contacted at their civilian address. In addition, amendments to the human protocol and ICD were completed to include a HIPAA authorization form generated that combined the forms used at Wilford Hall Medical Center and The University of Texas Southwestern Medical Center at Dallas. Appendix B includes the most

recently approved ICD. We are currently awaiting final IRB approval from Ft. Detrick prior to the formal enrollment of participants.

Finalize Recruitment Strategy and Begin Recruiting Subjects for the Project

We have also finalized the recruitment strategy and standard procedures to follow for enrollment of patients into the study. Recruitment of patients have been initiated. Anticipated start date for enrollment of patients into the study is 1 March 04.

Monitoring Any New Information Available Regarding the Major Goals of this Research Project

We have, and will continue to review, all recent literature concerning our study hypotheses. Our recent review of the literature has indicated that there still remains a paucity of studies evaluating the ICPRP as a treatment for chronic pain in a military population. Specifically, a literature review using MEDLINE, and PsychINFO has revealed no available published reports or analyzed control trial studies of ICPRP as a treatment for chronic pain in the military. Reviews of recent published studies continue to support the cost-and treatment-effectiveness of ICPRP as a treatment for civilians with both chronic and acute musculoskeletal pain.

KEY RESEARCH ACCOMPLISHMENTS

- Recruitment and training of all required project team members.
- Testing, revising, and finalizing all of the treatment protocols for the project.
- Development of the final assessment-outcome measures database that is being used in this project.
- Began subject recruitment.

REPORTABLE OUTCOMES

Because of the longitudinal nature of this investigation, insufficient data have yet been gathered to render any preliminary results or conclusions at this point in time, although current trends of the data are promising, and suggestive of positive outcomes.

CONCLUSIONS

Because we are only in the first year of this project, which is longitudinal in nature, we have come to no conclusions in our research. We have, however, met all of our goals for YEAR 01 of the project, in spite of the fact that there was some initial delay because of the Iraqi conflict at the beginning of the grant period. We are confident that the resulting data from this project will be vital in establishing a significantly efficacious and cost-effective way to treat chronic musculoskeletal pain among active duty military, a problem currently costing the Department of Defense billions of dollars each year in direct and indirect costs. Further possible benefits include decreased health-care utilization and improved quality of life for active duty soldiers suffering from chronic musculoskeletal pain disability.

REFERENCES

No new references included in this report.

APPENDICES

APPENDIX A: Summary of Outcome Measures in our Database

APPENDIX B: Most Recently Approved ICD

APPENDIX A

SUMMARY OF OUTCOME MEASURES IN OUR DATABASE

ICPRP Data Management System **Variable Coding Sheet**

*** Note: Any missing data (not asked, skipped by pt, unavailable, ambiguous, more than one non-numerical answer circled, etc..) = N/A*

1	Last Name		
2	First Name		
3	FMP/SSN	3a. ___ ___ / 3b. ___ ___ ___ -- ___ ___ -- ___ ___ ___ ___	
4	Group	3b. Patient Group: ICPRP = 1 Control = 2 CODE: _____	
5	Follow-up Projected	Projected Follow-up date for PRE-I / POST-1 / 6MO / 12MO / 18MO ___ ___ / ___ ___ / ___ ___ MM DD YY	
6	Follow-up Actual	Follow-up date for PRE-I / POST-I / 6MO / 12MO / 18MO ___ ___ / ___ ___ / ___ ___ MM DD YY	
7	Date of First Appointments	4a. Date First Seen By Anesth ___ ___ / ___ ___ / ___ ___ MM DD YY	4b. Date Finished Anesth Tx ___ ___ / ___ ___ / ___ ___ MM DD YY
8	Date of Injury – LOD	5a. Date pain began ___ ___ / ___ ___ / ___ ___ MM DD YY	5b. Date Of ICPRP Intake ___ ___ / ___ ___ / ___ ___ MM DD YY
9	Age in years	_____ N/A=-9 Date of Birth: ___ ___ / ___ ___ / ___ ___ MM DD YY	6b Duration of Symptoms in months for the chief complaint N/A= -9 ___ ___ ___
10	Service of Patient (or sponsor)	US Army = 1 US Air Force =2 US Navy = 3	US Marine =4 US Coast Guard =5 N/A=-9 CODE: ___
12	Patient's beneficiary	List of Values:	

	classification:	Active Duty.....1 Dependent of Active Duty.....2 Guard/Reserve.....3 Dependent of Guard/Reserve.....4 Retiree.....5 Dependent of Retiree.....6 Other.....7 Unknown .....8 N/A.....-9
13	Gender	Male.....1 Female.....2 N/A.....-9
14	Race Ethnic Code: Definition: The code which represents a non scientific division of the population based on assumed primordial biological properties combined with a segment population that possesses common characteristics and/or cultural heritage.	List of Values: American Indian or Alaskan Native.....1 Asian or Pacific Islander.....2 Black (not Hispanic).....3 White (not Hispanic).....4 Hispanic.....5 Other.....6 Unknown 7
15	Marital Status Code: Definition: The code that represents the	List of Values: Single, not married.....1 Married.....2

	marital status of the patient.	Divorced.....3 Legally Separated.....4 Widowed.....5 Annulled.....6 Not defined.....7 Unknown .....8 Interlocutory decree.....9 Never Married 10
16	Years Married	_____ N/A = -9
17	Kids	Yes = 1 NO = 2 N/A = -9 If Yes, Number: _____
18	Rank of patient (or rank of spouse if pt not AD)	E-1 = 01 E-6 = 06 O-2 = 11 O-7 = 16 E-2 = 02 E-7 = 07 O-3 = 12 O-8 = 17 E-3 = 03 E-8 = 08 O-4 = 13 O-9 = 18 E-4 = 04 E-9 = 09 O-5 = 14 O-10=19 E-5 = 05 O-1 =10 O-6 = 15 N/A = -9 CODE: ____ ____
19	Years of Service	_____ N/A = -9
20	Clearance Status (check all that apply)	__ PRP __ SCI Clearance __ Flying Status __ Weapons Bearing __ Top Secret
21	Years of Education	Number of years of education: _____ N/A = -9
22	Highest Degree Received	No degree = 01 G.E.D. = 02 High School = 03 High School + Some College/Tech School = 04 Associates = 05

		Bachelors = 06 Graduate = 07 N/A = -9
23	Referral Source (clinic)	Pain = 01 Neurology = 06 Hemat/Onc=11 Sleep = 02 Neuropsych = 07 Cardiology=12 Dental = 03 Ment Health = 08 Rheum =13 Prim Care=04 Internal Med = 09 Other =14 Pulmonary=05 Orthopedics = 10 N/A = -9 CODE: ____ ____
24	Other clinic	IF Above is OTHER, specify clinic: _____
25	Current Injury	Current pain due to injury where? Lumbar = 01 Multiple Spinal = 05 Thoracic = 02 Upper Extremity = 06 Cervical = 03 Lower Extremity = 07 Other = 08
26	Patient Described	How patient describes site of injury: _____
27	Previous Injury	Previous injury/pain resulting in inability to work? YES = 01 NO = 02 N/A = -9 If YES, where? Lumbar = 01 Multiple Spinal = 05 Thoracic = 02 Upper Extremity = 06 Cervical = 03 Lower Extremity = 07 Other = 08 CODE: ___ ___
28	New Injury	Sustained new injury/pain resulting in inability to work? YES = 01 NO = 02 N/A = -9 If YES, new injury to same site? YES = 01 NO = 02 N/A = -9 If NOT SAME SITE – Site of new injury: Lumbar = 01 Multiple Spinal = 05

		Thoracic = 02 Upper Extremity = 06 Cervical = 03 Lower Extremity = 07 Other = 08 CODE: ___ ___
29	Patient Described Previous Inj	How patient describes site of previous injury: _____
30	Drug Allergies	Are you allergic to any medications or food? YES = 01 NO = 02 N/A = -9 CODE: ___ ___
31	Health Care Visits	Total # of healthcare visits since pain began: _____ Total # of healthcare visits due to current injury/pain: _____
32	Type – Health Care Visits	Type of Visit(s)related to your pain: 00 None 06 Psychologist 01 Medical Doctor 07 Licensed Professional Counselor 02 Orthopedist 03 Physical Therapist 08 Massage Therapist 04 Chiropractor 09 Acupuncturist 05 Psychiatrist 10 Other Specialist CODE-1: ___ ___ CODE-2: ___ ___ CODE-3: ___ ___
33	Hospitalization	Were you hospitalized since pain began? YES = 01 NO = 02 N/A = -9 CODE: ___ ___
34	Hospitalization #	If YES, how many times hospitalized? # = _____ # days in hospital = _____
35	Pain Hospitalization #	How many times hospitalized due to current injury/pain? # = _____ # days in hospital = _____
36	Previous Passive Treatments?	Undergone any previous surgical/medical procedures for your pain since pain began? YES = 01 NO = 02 N/A = -9

		If YES, how many procedures? _____
37	Procedure 1	If 16-6 is YES, which procedure(s)? 01 = fusion 02 = morphine pump 03 = spinal cord stimulator 04 = injection(s) 05 = TENS unit 06 = Other _____ -9 = N/A CODE: ___ ___
38	Procedure 2	If 16-6 is YES, which procedure(s)? 01 = fusion 02 = morphine pump 03 = spinal cord stimulator 04 = injection(s) 05 = TENS unit 06 = Other _____ -9 = N/A CODE: ___ ___
39	Procedure 3	If 16-6 is YES, which procedure(s)? 01 = fusion 02 = morphine pump 03 = spinal cord stimulator 04 = injection(s) 05 = TENS unit 06 = Other _____ -9 = N/A CODE: ___ ___
40	Other Health Problems	Any other problems with your health not indicated above? YES = 01 NO = 02 N/A = -9 CODE: ___ ___
41	Sleep	17a. Average self-reported hours of sleep a night_____ N/A = -9 <u>Symptoms checked as occurring 3 or more days a week:</u> 17b.Difficulty falling asleep.....1 17c. Difficulty staying asleep.....2

		17d. Waking up earlier than planned.....3 17e. Restless legs.....4 17f. Excessive snoring.....5 17g. Taking sleep medication.....6 17h. Stop breathing briefly.....7 17i. Nightmares.....8 17j Excessive daytime sleepiness.....9 17k. Not feeling rested when you wake-up.....10
42	Sleep Efficiency	17.2 (Time Spent Asleep) (Time Spent in Bed) * 100 = _____%
43	Sexuality	Satisfaction from 0-10 with 10 = very satisfied: N/A = -9 Code 11 if the marked "I prefer not to answer." CODE:_____
44	Alcohol Use	19a. Trouble with alcohol in the past? Yes=1 No=2 N/A = -9 19b. Current Use: Yes =1 No =2 N/A = -9 If Yes: 19c. Average number of drinks per week: _____ 19d. Have you ever felt you should cut down on your drinking? Yes=1 No=2 19e. Have people annoyed you by criticizing your drinking? Yes=1 No=2 19f. Have you ever felt bad or guilty about your drinking? Yes=1 No=2 19g. Have you ever had a drink first thing in the morning to steady your nerves or get rid of a hangover (e.g. eye opener)? Yes=1 No=2 19h. CAGE score (0-4)_____

45	Current (past 30 days) Tobacco Use Status	20a. Not current tobacco user = 01 Prior tobacco user = 02 Current tobacco user (any daily use) = 03 N/A = -9 20b. <u>If yes to current tobacco use:</u> Type of tobacco Cigarettes = 01 Pipe/Cigar = 02 Smokeless = 03 20c. Duration of Tobacco Use in Years:_____
46	Current Caffeine Use	21a. Yes =01 No =02 N/A = -9 21b. <u>If Yes:</u> Average number of drinks per week: _____
47	BMI	22-1a. Height (inches) _____ 22-1b. Weight (pounds) _____
48	Diet	22-2. Currently on a diet trying to lose wt? Yes = 01 No = 02 N/A = -9
49	Diet – 2	Do you eat too much/too little? YES = 1 NO = 2 N/A = -9
50	Exercise on Regular Basis	Yes = 1 No = 2 N/A = -9
51	History of Mental Health Treatment (any tx the pt indicated as MH including Chaplain, etc...)	Yes = 1 No = 2 N/A = -9
52	History of Physical,	

	Sexual, or Emotional abuse	Yes = 1 No = 2 N/A = -9
53	Satisfaction with Social Support from Family & Friends	Very Unsatisfied.....1 Unsatisfied.....2 Satisfied.....3 Very Satisfied.....4 N/A.....-9
54	Hours Worked	How many hours a week, on average, do you work? _____
55	Job History	26a. Disability/Workers Comp: Yes = 1 No = 2 N/A = -9 <u>26b. Work Status:</u> Full-time outside the home.....1 Full-time in the home.....2 Part-time.....3 Retired.....4 N/A.....-9 <u>26c. Job Title:</u> What is your current job title? _____ <u>26c. If Working, Satisfaction with Current Occupation:</u> Very Unsatisfied.....1 Unsatisfied.....2 Satisfied.....3 Very Satisfied.....4 N/A.....-9
56	Return to Work	<u>Present Vocational Status:</u> 01 RTW, Full Time, Same Job Type 02 RTW, Full Time, New Job Type 03 RTW, Light/Part Duty, Same Job Type

		04 RTW, Light/Part Duty, New Job Type **05 RTW, But Not Pres Worki BC of New Injury** 06 RTW, But Not Pres Work BC Original Injury 07 Self-Employed 08 Vocational Training or School/Retraining 09 Never Returned to Work Because of Injury 10 Denies Work BC of Employment Factors Exc 11 Denies Work, But Engag in Incom Prod Act 12 Denies Work,Participates Non-Income Prod Activities 13 Was Not Working Before Injury
57	RTW Date	Date pt returned to work: ___ ___ / ___ ___ / ___ ___ MM DD YY
58	Quality of Life	Satisfaction with Quality of Life: Very Unsatisfied.....1 Unsatisfied.....2 Satisfied.....3 Very Satisfied.....4 N/A.....-9
59	Spirituality	28a. Importance from 0-10 with 10 = very important: ____ N/A=-9 28b. Current difficulties affecting spirituality: Yes = 1 No= 2
60	Legal Issues	Current litigation pending concerning pt's condition: Yes = 1 No= 2 N/A=-9
61	Disciplinary Action	Any history of disciplinary action (e.g., LOC, LOR, LOA)? YES = 01 NO = 02 N/A = -9
62	Goals	Top Three Goals from Goal sheet (1-51) 1:____ 2:____ 3:____ N/A=-9
63	PrimaryAxis I Diagnosis	296.2 MD, sing ep = 01 316 Psych fac/Med Cond= 06 296.3 MD, recurrent = 02 V71.09 No diagnosis = 07

		307.xx Pain Disorder = 03 799.9 Deferred = 08 307.42 Prim Insomnia = 04 Other Diagnosis = 09 309.xx Adjustment DO= 05 PTSD = 10 GAD = 11 Panic Dis = 12 N/A=-9 CODE: ____ ____
64	Other diagnosis	IF above is OTHER, specify diagnosis:
65	Secondary Axis I Diagnosis if appropritate	296.2 MD, sing ep = 01 316 Psych fac/Med Cond= 06 296.3 MD, recurrent = 02 V71.09 No diagnosis = 07 307.xx Pain Disorder = 03 799.9 Deferred = 08 307.42 Prim Insomnia = 04 Other Diagnosis = 09 309.xx Adjustment DO= 05 N/A=-9 CODE: ____ ____
66	Other diagnosis	IF above is OTHER, specify diagnosis:
67	Primary Axis III (Choose ONE most directly related to referral)	Headache=01 Fibromyalgia = 08 Myofac. Pain = 15 RSD/CRPS=02 HTN= 09 Other = 16 IBS = 03 Other chron pain=10 N/A=-9 TMD = 04 Cardiac = 11 COPD = 05 Cancer =12 Arthritis = 06 Obesity = 13 Chron Back= 07 Insomnia = 14 CODE: ____ ____
68	Other Axis III	IF above is OTHER, specify diagnosis:

69	Secondary Axis III	Headache=01 Fibromyalgia = 08 Myofac. Pain = 15 RSD/CRPS=02 HTN= 09 Other = 16 IBS = 03 Other chron pain=10 N/A=-9 TMD = 04 Cardiac = 11 COPD = 05 Cancer =12 Arthritis = 06 Obesity = 13 Chron Back= 07 Insomnia = 14 CODE: ____ ____
70	Other Axis III	IF above is OTHER, specify diagnosis:
71	Site Treated	WHMC = 01 BAMC = 02 CODE: ____ ____

JOB REQUIREMENTS EVALUATION

72	Standing	Indicate the amount of time spent at your job doing this activity: NONE = 01 OCCASIONAL = 02 FREQUENT = 03 CONSTANT = 04 CODE: ___ ___
73	Walking	Indicate the amount of time spent at your job doing this activity: NONE = 01 OCCASIONAL = 02 FREQUENT = 03 CONSTANT = 04 CODE: ___ ___
74	Sitting	Indicate the amount of time spent at your job doing this activity: NONE = 01 OCCASIONAL = 02 FREQUENT = 03 CONSTANT = 04 CODE: ___ ___
75	Squatting	Indicate the amount of time spent at your job doing this activity: NONE = 01 OCCASIONAL = 02 FREQUENT = 03 CONSTANT = 04 CODE: ___ ___
76	Kneeling	Indicate the amount of time spent at your job doing this activity: NONE = 01 OCCASIONAL = 02 FREQUENT = 03 CONSTANT = 04 CODE: ___ ___
77	Stooping/Bending	Indicate the amount of time spent at your job doing this activity: NONE = 01 OCCASIONAL = 02 FREQUENT = 03 CONSTANT = 04 CODE: ___ ___
78	Crawling	Indicate the amount of time spent at your job doing this activity: NONE = 01 OCCASIONAL = 02 FREQUENT = 03 CONSTANT = 04 CODE: ___ ___
79	Driving	Indicate the amount of time spent at your job doing this activity: NONE = 01 OCCASIONAL = 02 FREQUENT = 03 CONSTANT = 04 CODE: ___ ___
80	Repetitive Handwork	Indicate the amount of time spent at your job doing this activity: NONE = 01 OCCASIONAL = 02 FREQUENT = 03 CONSTANT = 04 CODE: ___ ___
81	Reaching	Indicate the amount of time spent at your job doing this activity: NONE = 01 OCCASIONAL = 02 FREQUENT = 03 CONSTANT = 04 CODE: ___ ___
82	Lifting	Indicate the amount of time spent at your job doing this activity: NONE = 01 OCCASIONAL = 02 FREQUENT = 03 CONSTANT = 04 CODE: ___ ___
83	Carrying	Indicate the amount of time spent at your job doing this activity: NONE = 01 OCCASIONAL = 02 FREQUENT = 03 CONSTANT = 04 CODE: ___ ___
84	Pushing/Pulling	Indicate the amount of time spent at your job doing this activity: NONE = 01 OCCASIONAL = 02 FREQUENT = 03 CONSTANT = 04 CODE: ___ ___
85	Climbing	Indicate the amount of time spent at your job doing this activity: NONE = 01 OCCASIONAL = 02 FREQUENT = 03 CONSTANT = 04 CODE: ___ ___

PSYCHOSOCIAL TEST DATA

Reminder: Any missing data (unavailable, ambiguous, more than answer circled, etc..) = N/A

86	BDI – Front	____ ____		102	MPIPS	____ ____ . ____ ____
87	BDI - Back	____ ____		103	MPII	____ ____ . ____ ____
88	BDI - Total	____ ____		104	MPILC	____ ____ . ____ ____
89	BDI – Item 9	____ ____		105	MPIAD	____ ____ . ____ ____
90	SF36 – PF	____ ____		106	MPIS	____ ____ . ____ ____
91	SF36 – RP	____ ____		107	MPIPR	____ ____ . ____ ____
92	SF36 – BP	____ ____		108	MPISR	____ ____ . ____ ____
93	SF36 – GH	____ ____		109	MPIDR	____ ____ . ____ ____
94	SF36 – VT	____ ____		110	MPIHC	____ ____ . ____ ____
95	SF36 – SF	____ ____		111	MPIOW	____ ____ . ____ ____

96	SF36 – RE	_____ _____		112	MPIAAH	____ ____ . ____ ____
97	SF36 – MH	_____ _____		113	MPISA	____ ____ . ____ ____
98	SF36 – PCS	_____ _____		114	MPIGA	____ ____ . ____ ____
99	SF36 – MCS	_____ _____		115	MPI Profile	Dysfunctional…….1 Interpers/Distr……2 Adaptive Cop……..3 Anomolous……..…4 Hybrid……5 Unanalyzable…….6
100	SF36 – PCS %	_____ _____				
101	SF36 – MCS %	_____ _____		116	PCI	High: _____ Low: _____ AVG: _____

Reminder: Any missing data (unavailable, ambiguous, more than answer circled, etc..) = N/A

117	SF36q1	_____ _____		133	SF36q17	____ ____ . ____ ____

118	SF36q2			134	SF36q18	
119	SF36q3			135	SF36q19	
120	SF36q4			136	SF36q20	
121	SF36q5			137	SF36q21	
122	SF36q6			138	SF36q22	
123	SF36q7			139	SF36q23	
124	SF36q8			140	SF36q24	
125	SF36q9			141	SF36q25	
126	SF36q10			142	SF36q26	
127	SF36q11			143	SF36q27	
12	SF36q12			14	SF36q28	

8				4		
129	SF36q13			145	SF36q29	
130	SF36q14			146	SF36q30	
131	SF36q15			147	SF36q31	
132	SF36q16			148	SF36q32	

149	SF36q33	_____ _____		164	THQgc	____ ____ . ____ ____
150	SF36q34	_____ _____		165	FABQpa	____ ____ . ____ ____
151	SF36q35	_____ _____		166	FABQw	____ ____ . ____ ____
152	SF36q36	_____ _____		167		____ ____ . ____ ____
153	MVAS	_____ _____		168	PainVAS	____ ____ . ____ ____
154	MVAScat	0 = None (MVAS = 0) 1 = Mild (1-40) 2 = Moderate (41-70) 3 = Severe (71-100) 4 = Very Severe (101-130) 5 = Extreme (131-150) -9 = no MVAS score		169	POMStot	____ ____ . ____ ____
				170	POMSanx	____ ____ . ____ ____
155	THQwp	_____ _____		171	POMSdep	____ ____ . ____ ____
156	THQmed	_____ _____		172	POMSang	____ ____ . ____ ____
15	THQpsy			17	POMSvig	

7				3		
158	THQpt			174	POMSfat	
159	THQdr			175	POMScon	
160	THQip			176		
161	THQdiag			177		
162	THQwat			178	ORQtot	
163	THQpe			179	ORQdep	

180	ORQpi		
181	ORQdwr		
182	ORQpwh		
183	ORQssw		
184	ORQwsl		
185	ORQwks		
186	ORQfss		
187	ORQppwr		
188	PCLM		
189	OSW		
190	ISI		

19 1	CEQ		

DSM-IV AXIS I DIAGNOSIS

192	AxisId1	1 = Major Dep – Single Episode (296.2) 2 = Major Dep – Recurrent (296.3) 3 = Pain Disorder (307.xx) 4 = Primary Insomnia (307.42) 5 = Adjustment Disorder (309.xx) 6 = Psych Fac to Med Cond (316) 7 = Gen Anx Dis (300.02) 8 = PTSD (309.81) 9 = Panic Disorder (300.2x) 10 = Deferred (799.9) 11 = No Diagnosis (V71.09) 12 = Other Diagnosis -9 = N/A
193	AxisId2	1 = Major Dep – Single Episode (296.2) 2 = Major Dep – Recurrent (296.3) 3 = Pain Disorder (307.xx) 4 = Primary Insomnia (307.42) 5 = Adjustment Disorder (309.xx) 6 = Psych Fac to Med Cond (316) 7 = Gen Anx Dis (300.02) 8 = PTSD (309.81) 9 = Panic Disorder (300.2x) 10 = Deferred (799.9) 11 = No Diagnosis (V71.09) 12 = Other Diagnosis -9 = N/A
194	AxisId3	1 = Major Dep – Single Episode (296.2) 2 = Major Dep – Recurrent (296.3) 3 = Pain Disorder (307.xx) 4 = Primary Insomnia (307.42) 5 = Adjustment Disorder (309.xx) 6 = Psych Fac to Med Cond (316) 7 = Gen Anx Dis (300.02) 8 = PTSD (309.81) 9 = Panic Disorder (300.2x) 10 = Deferred (799.9) 11 = No Diagnosis (V71.09) 12 = Other Diagnosis -9 = N/A

195	Tflex		
196	Text		
197	PILEwt-waist		
198	PILEhr-waist		
199	PILEwt-shoulder		
200	PILEhr-shoulder		
201	Aerovo2		
202	Aerotime		
203	Aerohr		
204	Aeroefft		
205	GripstrL		

206	GripstrR	_____	
207	DomHand	*Circle one:* **Left** **Right**	

Past Treatment Received

Reminder: Any missing data (unavailable, ambiguous, etc..) = N/A

208	Individual	No.....0 Yes.....1 Intake Only .....2 Number of Sessions:_____
209	Biofeedback	No.....0 Yes.....1 Number of Sessions:_____
210	Interdisciplinary Chronic Pain Management Program *or* Interdisciplinary Chronic Pain Rehabilitation Program Pain Group	No.....0 Yes.....1 Number of Sessions:_____
211	4-session Pain Group or similar	No.....0 Yes.....1 Number of Sessions:_____
212	TMD Group	No.....0 Yes.....1 Number of Sessions:_____
213	COPD (Pulmonary Rehab Group)	No.....0 Yes.....1 Number of Sessions:_____
214	LEARN	No.....0

		Yes.....1 Number of Sessions:_____
215	Behavioral Cardiac Rehab Program	No.....0 Yes.....1 Number of Sessions:_____
216	Tobacco Cessation Program	No.....0 Yes.....1 Number of Sessions:_____
217	Relaxation Group	No.....0 Yes.....1 Number of Sessions:_____
218	Insomnia Group	No.....0 Yes.....1 Number of Sessions:_____
219	Previous Passive Treatments?	Undergone any previous surgical/medical procedures for your pain since pain began? YES = 01 NO = 02 N/A = -9 If YES, how many procedures? _____
220	Procedure 1	If 16-6 is YES, which procedure(s)? 01 = fusion 02 = morphine pump 03 = spinal cord stimulator 04 = injection(s) 05 = TENS unit

		06 = Other _____ -9 = N/A CODE: ___ ___
221	Procedure 2	If 16-6 is YES, which procedure(s)? 01 = fusion 02 = morphine pump 03 = spinal cord stimulator 04 = injection(s) 05 = TENS unit 06 = Other _____ -9 = N/A CODE: ___ ___
222	Procedure 3	If 16-6 is YES, which procedure(s)? 01 = fusion 02 = morphine pump 03 = spinal cord stimulator 04 = injection(s) 05 = TENS unit 06 = Other _____ -9 = N/A CODE: ___ ___

Post-FORT Treatment(s) Received

Reminder: Any missing data (unavailable, ambiguous, etc..) = N/A

223	Individual	No.....0 Yes.....1 Intake Only .....2 Number of Sessions:_____
224	Biofeedback	No.....0 Yes.....1 Number of Sessions:_____
225	Interdisciplinary Chronic Pain Management Program *or* Interdisciplinary Chronic Pain Rehabilitation Program Pain Group	No.....0 Yes.....1 Number of Sessions:_____
226	4-session Pain Group or similar	No.....0 Yes.....1 Number of Sessions:_____
227	TMD Group	No.....0 Yes.....1 Number of Sessions:_____
228	COPD (Pulmonary Rehab Group)	No.....0 Yes.....1 Number of Sessions:_____
229	LEARN	No.....0 Yes.....1

		Number of Sessions:_____
230	Behavioral Cardiac Rehab Program	No.....0 Yes.....1 Number of Sessions:_____
231	Tobacco Cessation Program	No.....0 Yes.....1 Number of Sessions:_____
232	Relaxation Group	No.....0 Yes.....1 Number of Sessions:_____
233	Insomnia Group	No.....0 Yes.....1 Number of Sessions:_____
234	Passive Treatments?	Undergone any previous surgical/medical procedures for your pain since completing the FORT program? YES = 01 NO = 02 N/A = -9 If YES, how many procedures? _____
235	Procedure 1	If 16-6 is YES, which procedure(s)? 01 = fusion 02 = morphine pump 03 = spinal cord stimulator 04 = injection(s) 05 = TENS unit

		06 = Other _____ -9 = N/A CODE: ___ ___
236	Procedure 2	If 16-6 is YES, which procedure(s)? 01 = fusion 02 = morphine pump 03 = spinal cord stimulator 04 = injection(s) 05 = TENS unit 06 = Other _____ -9 = N/A CODE: ___ ___
237	Procedure 3	If 16-6 is YES, which procedure(s)? 01 = fusion 02 = morphine pump 03 = spinal cord stimulator 04 = injection(s) 05 = TENS unit 06 = Other _____ -9 = N/A CODE: ___ ___

APPENDIX B

MOST RECENTLY APPROVED ICD

BROOKE ARMY MEDICAL CENTER/WILFORD HALL MEDICAL CENTER
INFORMED CONSENT DOCUMENT
(ICD Template Version 4. Feb 02)

A Randomized Trial of Musculoskeletal Pain Treatment in a Military Population

PRINCIPAL INVESTIGATOR – Lt Col Alan L. Peterson

If you choose not to participate in this research study, your decision will not affect your eligibility for care or any other benefits to which you are entitled.

DESCRIPTION/PURPOSE OF RESEARCH
You are being asked to consider participation in this research study. The purpose of this study is to evaluate the effectiveness of two different treatments designed to decrease chronic pain, increase functioning, and retain military members on active duty.

This study is being conducted at Wilford Hall Medical Center in San Antonio, Texas and Brooke Army Medical Center, San Antonio, Texas. The study will enroll approximately 90 active duty military personnel with musculoskeletal pain over a period of 18 months. The overall duration of the study will be about 4 years, but the time requirement for individual participants will be about four weeks with follow-up evaluations occurring at 6 months, 12 months, and 18 months.

The two approaches to pain management that will be evaluated in this study are as follows:

Group A, Standard Anesthesia Pain Clinic Medical Care: Participants in this group will be thoroughly evaluated by physicians trained in medical pain management techniques. Appropriate medical recommendations will be made and may include any of the following: pain medications, antidepressant medications, and nerve block and steroid injections. This treatment will include about 6 patient visits over a three-week period.

Group B, Standard Anesthesia Pain Clinic Medical Care AND Interdisciplinary Chronic Pain Rehabilitation Program: This group will receive all of the treatment as described in

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Group A above, as well as an interdisciplinary functional restoration treatment program, which consists of three major components. Each participant will be evaluated and treated by physical therapy, occupational therapy, and clinical health psychology in coordination with a supervising nurse-physician team. This group will include 3 weeks of full-time treatment including supervised physical exercise and learning pain management skills.

RANDOMIZATION OF STUDY PARTICIPANTS: As a participant, you will be randomly assigned to one of these two groups. Randomization is a process much like flipping a coin and means you will have the same chance of being assigned to either of these two groups.

PROCEDURES: As a participant, you will undergo the following procedures:

Meeting One: The first meeting with Clinical Health Psychology service will involve a full assessment of your pain condition. You will then receive an overview of the study, complete the informed consent document, and be asked to complete several questionnaires about your functioning in many areas (estimated time 1 1/2 hours).

During the first session you will also be randomly assigned to one of the two groups. If you are assigned to Group A or B, you will be treated at the Anesthesia Pain Clinic at Wilford Hall or Brooke Army Medical Center as directed by your physicians. Should it be necessary for you to have a standard anesthesia pain clinic treatment requiring additional informed consent, a separate consent form will be completed at the time of the procedure. If you are selected for Group B, you will also be scheduled for inclusion in the Interdisciplinary Chronic Pain Rehabilitation Program. This three-week program will be offered at Wilford Hall Medical Center once each month.

Phone Contacts and Mailings: Participants in both Groups A and B will be contacted for follow-up information 3 weeks after the initiation of treatment and then at the 6 month, 12 month and 18 month point. Each of these follow-up contacts will involve gathering the same information on functioning as previously assessed. I understand that if I am no longer on active duty in the U.S. military at the time of one of my follow-up assessments, I will be contacted at my civilian address to request completion of the outcome questionnaires.

Should it be necessary for you to have a procedure requiring additional informed consent, a separate consent form will be completed at the time of the procedure.

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RISKS OR DISCOMFORTS:

There is minimal psychological and/or physical risk from the early interventions to be used in this study. In past research, none of the subjects had any problems. You could experience stress from participating in this kind of research. Knowing that researchers have personal information about you may trouble you. There is a possibility that your low back pain may worsen if you are assigned to the early intervention; however, this is not anticipated.

For those in Group A and B, the risks and discomforts of participating are the same as those that would be expected when under the care of the Anesthesia Pain Clinic for any other patient. An additional informed consent for a standard anesthesia pain clinic treatment may be obtained at the time of treatment. These treatments include the use of medications and injections, and the potential adverse effects include infection, bleeding, nerve damage, allergic reactions and either no change or a worsening of your pain.

For those in Group B, there are some risks, which involve engaging in a functional restoration program although these are expected to be minimized since you will be following the recommendations of an interdisciplinary staff of healthcare providers (e.g., physician, nurse, psychologist, physical therapist, and occupational therapist). It is also possible that your pain could become somewhat worse during the course of treatment. There may also be unforeseen risks associated with this study. A previously unknown problem could result from your participation in this research. It is not possible to estimate the chances of such problems or how serious problems could be. Consequently, we ask that you inform the study doctor or any of the Investigators listed on this form of any problems that arise during this study, and also inform your physician. Finally, if suicidality is ever indicated, your commander will be notified and appropriate action will be taken.

BENEFITS:

While there is no guarantee you will benefit from participating in this study, it is intended to reduce your pain, increase your functioning, and retain your active duty status. The treatments are believed to be beneficial, and how well they work is the focus on this study. The investigators have designed this study to learn if there is a difference and how they can better treat active duty members who often times are concerned about their ability to remain in the military until they decide to retire.

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There will also be a scientific benefit if this study can tell us which treatment for musculoskeletal pain is better.

PAYMENT (COMPENSATION):
You will not receive any compensation (payment) for participating in this study.

ALTERNATIVES TO PARTICIPATION: Alternatives may be available to you, including other pain management programs or individual consultations with Physical Therapy, Occupational Therapy, Mental Health, or Clinical Health Psychology available through your medical treatment facility. Other alternatives would be to seek follow-up care with your primary care manager or to participate in treatment at the Anesthesia Pain Clinic but to decline participation in the data collection or to decline any treatment at all.

CONFIDENTIALITY OF RECORDS OF STUDY PARTICIPATION:
Records of your participation in this study may only be disclosed in accordance with federal law, including the Federal Privacy Act, 5 U.S.C. 552a, and its implementing regulations. DD Form 2005, Privacy Act Statement- Military Health Records, contains the Privacy Act Statement for the records. By signing this consent document, you give your permission for information gained from your participation in this study to be published in medical literature, discussed for educational purposes, and used generally to further medical science. You will not be personally identified; all information will be presented as anonymous data.

Your records may be reviewed by the U.S. Food & Drug Administration (FDA), other government agencies, the BAMC/WHMC Institutional Review Boards, and by research staff. Complete confidentiality cannot be promised, particularly for military personnel, because information regarding your health may be required to be reported to appropriate medical or command authorities.

ENTITLEMENT TO CARE:

In the event of injury resulting from this study, the extent of medical care provided is limited and will be within the scope authorized for Department of Defense (DoD) health care beneficiaries.

Your entitlement to medical and dental care and/or compensation in the event of injury is governed by federal laws and regulations, and if you have questions about your rights as a research subject or

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if you believe you have received a research-related injury, you may contact the Wilford Hall Clinical Research Squadron Commander, (210) 292-7069 or Wilford Hall Medical Center Risk Manager, 210-292-6004.
Brooke Army Medical Center Protocol Coordinators, 210-916-2598 or BAMC Judge Advocate, 210-916-2031.

Preparation in this study does not alter your ongoing medical benefits as a military beneficiary, and you will continue to receive any needed medical treatment should you experience illness or injury as a result of this study. In the event of injury resulting from the investigational procedures, the extent of medical care provided is limited and will be within the scope authorized for DoD health care beneficiaries.

BLOOD & TISSUE SAMPLES: "No blood or tissue samples will be taken as part of this study."

STATEMENT OF GOOD FAITH: The investigator cannot guarantee or promise that you will receive benefits from this study; however, the investigator will keep you informed of any serious complications, which may result from your participation in this study.

VOLUNTARY PARTICIPATION:
The decision to participate in this study is completely voluntary on your part. No one has coerced or intimidated you into participating in this project. You are participating because you want to. Lt Col (Dr) Alan Peterson, (Wilford Hall Medical Center, DSN 554-5968, Commercial (210) 292-5968), Dr. Robert Gatchel, (University of Texas Southwest Medical Center, Dallas, (214) 648-5277), or one of their associates has adequately answered any and all questions you have about this study, your participation, and the procedures involved. Dr. Peterson, Dr. Gatchel, or a member of the Clinical Health Psychology staff at Wilford Hall Medical Center ((210) 292-5968) will be available to answer any questions concerning procedures throughout this study. If significant new findings develop during the course of this study that may relate to your decision to continue participation, you will be informed.

You may withdraw this consent at any time and discontinue further participation in this study without affecting your eligibility for care or any other benefits to which you are entitled. Should you choose to
withdraw, you must inform one of the investigators. Your condition will continue to be treated in accordance with acceptable standards of medical treatment.

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The investigator of this study may terminate your participation in this study at any time if he/she feels this to be in your best interest. Your consent to participate in this study is given on a voluntary basis. All oral and written information and discussions about this study have been in English, a language in which you are fluent.

CONTACT INFORMATION:

Principal Investigator (PI)
The principal investigator or a member of Clinical Health Psychology staff will be available to answer any questions concerning procedures throughout this study.

Principal Investigator: Lt Col Alan L. Peterson Phone: (210) 292-5968

Institutional Review Board (IRB)
The WHMC Institutional Review Board (IRB), the hospital committee responsible for safeguarding your rights as a research subject, has assigned a member of the IRB, who is not part of the study team, to serve as an outside monitor for this study (this person is the Medical Monitor). If you have any questions about your rights as a research subject or any other concerns that cannot be addressed by the PI, you can contact the medical monitor, Joseph Schmelz, PhD, RN at (210) 292-5687. Or mail to: 59th Clinical Research Squadron/MSRP, 1255 Wilford Hall Loop, Lackland Air Force Base, Texas 78236.

In addition, if you have any comments, questions, concerns or complaints, you may also contact the Chairperson of the IRB, at (210) 292-7558. Or mail to: 59th Medical Wing/CM, 2200 Bergquist Drive, Lackland Air Force Base, Texas 78236.

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A copy of this form has been given to you.

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VOLUNTEER'S SIGNATURE **VOLUNTEER'S SSN** **DATE**

VOLUNTEER'S PRINTED NAME **FMP** **SPONSOR'S SSN** **DOB**

VOLUNTEER'S ADDRESS (street, city, state, zip)

ADVISING INVESTIGATOR'S SIGNATURE **DATE** **(PHONE NUMBER)**
(can only be signed by an investigator whose name is listed in the protocol)

PRINTED NAME OF ADVISING INVESTIGATOR

WITNESS' SIGNATURE **DATE**
(Must witness ALL signatures)

PRINTED NAME OF WITNESS

TITLE OF STUDY: A Randomized Trial of Musculoskeletal Pain Treatment in a Military Population
Protocol #:
Date Protocol Approved by WHMC/BAMC IRB:
Date(s) ICD Changes Approved by WHMC/BAMC IRB:

Subject's Stamp Plate
PRIVACY ACT OF 1974 APPLIES
DD FORM 2005 FILED IN MILITARY HEALTH RECORDS

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